PATENT SPECIFICATION

(11) 1 591 117

1 591 117

(21) Application No. 39303/77 (22) Filed 21 September 1977
(31) Convention Application No. 732232 (32) Filed 14 October 1977 in (19)
(33) United States of America (US)
(44) Complete Specification Published 17 June 1981
(51) INT. CL.^{3} B01D 13/00
(52) Index at Acceptance
B1X 6B2 6B3 6F5 6F6 6GX 6J2 6J3

(54) DISTRIBUTION SYSTEM OF BLOOD TREATMENT APPARATUS

(71) We, BAXTER TRAVENOL LABORATORIES INC., a Corporation organised and existing under the Laws of the State of Delaware, United States of America, of One Baxter Parkway, Deerfield, Illinois 60015, United States of America, do hereby declare the invention for which we pray that a Patent may be granted to us and the method by which it is to be performed to be particularly described in and by the following statement:–

The present invention relates to blood treatment apparatus, and more particularly, apparatus for dialyzing or oxygenating blood utilizing the transfer of fluid through a membrane.

A prior art type of transfer device includes (a) a plurality of fluid distribution plates with a pair of membranes interposed between each pair of plates, and (b) blood distribution buttons compressed between each plate for permitting the flow of blood through radial distribution channels defined by the buttons and between membranes while dialysate or oxygen flow is provided in the volume between the plate and the opposite side of the membrane. This type of dialyzer or oxygenator requires relatively thick plates and also requires that the casing supply compressive forces to close the stack of membranes and plates. Further, the necessity of having a plurality of blood buttons with distribution channels is detrimental to compactness of the system and forces the blood to flow through a tortuous path within the blood button which is detrimental to the optimization of a system in which the blood has smooth, laminar flow.

It is, therefore, an object of the invention to provide blood treatment apparatus in which the apparatus size can be kept relatively small and the casing (i.e., housing) does not have to supply compressive forces to the blood manifolds, thereby permitting the casing to be relatively small and light.

The invention obviates the use of blood buttons having internal radial distribution channels and allows the blood to flow smoothly without being forced through a tortuous path within a blood manifold.

In Meyers, et al. U.S. Patent No. 3,464,562 and Critchell, et. al. U.S. Patent No. 3,501,010, dialyzing apparatus is disclosed in which blood manifolding occurs on a side of the membrane support plates and the blood manifold system does not extend through the membranes and membrane support plates. In order to accomplish the construction disclosed in Meyers, et al. and Critchell, et al., however, the membranes have to be centered precisely within the frame during construction. For example, Figures 5-6 of Critchell, et al. and column 3, line 59 to column 4, line 14 of Critchell, et al. are illustrative of the precision required in constructing the apparatus.

In Dutch patent specification No. 7504359 in the name of Gambro AG, filed April 11, 1975, and disclosed October 20, 1975, a dialysis system is suggested in which membranes between membrane support plates are heat sealed to each other at the dialysate manifold port. By scaling the dialysate distribution manifold, however, the transmembrane pressure differential tends to place the seal in peel. We have discovered a means for overcoming this disadvantage, and in the present invention the membranes on opposite sides of a membrane support plate are sealed to each other at the blood manifold port, whereby the transmembrane pressure differential does not place stress on the seal and, in fact, the transmembrane pressure differential is favorable to maintaining the seal.

In accordance with the present invention, there is provided apparatus for the treatment of blood by means of a membrane comprising a first membrane support plate and a second membrane support plate each having means on opposite sides thereof for supporting a membrane and forming open volumes therebetween; first and second membranes supported on opposite sides of said first membrane support plate; third and fourth membranes supported on opposite sides of said second membrane support plate; said second membrane to form a blood path between said second and third membranes; said volumes between each membrane support plate and each adjacent membrane comprising a fluid flow path, said membranes having apertures; a blood manifolding path which extends through said membrane support plates and through the apertures in the membranes; first closing means closing said first and second membranes together around the apertures therein; second closing means closing said third and fourth membranes together around the apertures therein; said first and second closing means each operating to segregate the blood path and said fluid flow path, said first, and second closing means being spaced from each other to define a blood path therebetween and being independent of each other whereby the closing forces generated by said first closing means on said first and second membranes are independent of the closing forces generated by said second closing means on the third and fourth membranes.

The invention also provides apparatus for effecting the treatment of blood by means of a stack of parallely disposed membranes, comprising means for isolating respective blood and treatment fluid compartments from each other in a blood manifold region, said isolating means comprising means for closing a first and second membrane about a first membrane support plate, means for closing a third and fourth membrane about a second membrane support plate, said second and third membranes facing each other to define a blood flow path therebetween, fluid distribution volumes defined between each membrane and its associated membrane support plate said closing means being spaced from each other and defining a flow path between the second and third membranes, the closing means defining a blood manifolding path extending through said closing means membranes and membrane support plates without radial distribution channels in the closing means, said blood manifolding path permitting the blood to flow in the spacings between said closing means for flow between the membranes facing each other.

The invention also resides in an apparatus for the treatment of blood by means of a membrane comprising a stack of parallel membranes and membrane support plates with each membrane support plate having a membrane positioned on opposite sides thereof; a blood manifolding path extending through said membranes; closing means sealing the membranes on opposite sides of each membrane support plate to each other around said blood manifolding path, said closing means being spaced from each other to define a blood path therebetween and being independent of each other whereby the closing forces generated by one of the closing means on its respective membranes are independent of the closing forces generated by other closing means on their respective membranes.

In one embodiment, the first closing means and the second closing means each comprise a sealed grommet defining an axial bore extending through the grommet and forming a portion of the blood manifolding path.

Reference is now made to the accompanying drawings, wherein:-

Figure 1 is a fragmentary, enlarged cross-sectional view of a distribution system constructed in accordance with the present invention. The view includes parts of support plates, each of which, as shown, corresponds to a view along the plane of the line 1-1 of Figure 4;

Figure 2 is an enlarged cross-sectional view of a grommet of the type which can be used in the distribution system of Figure 1;

Figure 3 is a fragmentary, cross-sectional view of a membrane support plate with a pair of membranes being supported thereby;

Figure 4 is a top plan view of one-half of a membrane support plate;

Figure 5 is a fragmentary bottom plan view of the membrane support plate half of Figure 4;

Figure 6 is a fragmentary enlarged view of the fluid distribution channels of the membrane support plate;

Figure 7 is a fragmentary enlarged view of a portion of the membrane support plate of Figure 4;

Figure 8 is a fragmentary enlarged view of a portion of the membrane support plate of Figure 4;

Figure 9 is an enlarged cross-sectional view taken along the plane of the line 9-9 of Figure 4; and

Figure 10 is a fragmentary enlarged cross-sectional view taken along the plane of the line 10-10 of Figure 4.

Referring to Figures 1-3, there is shown a distribution system for fluid treatment apparatus comprising a plurality of membrane support plates, each of which membrane support plates supports a membrane on an opposite side thereof. As shown most clearly in Figure 1, a first membrane support plate 20 is formed of two identical halves 20*a* and 20*b*. Referring to Figure 4, it is seen that membrane support plate half 20*a* has a membrane support surface 22 and Figure 5 shows the underside thereof, which is a planar surface 24. Membrane support plate half 20*b*, which is identical to membrane support plate half 20*a*, has its corresponding planar underside abutting the planar underside 24 of membrane support plate half 20*a* to form first membrane support plate 20.

Since all of the membrane support plates are identical in construction, only membrane support plate 20 need be discussed in detail. It can be seen that membrane support plate 20 has oppositely positioned membrane support surfaces 22 which carry a plurality of cones 26 upon which membranes 28 and 30 are supported. Further, an open volume 32 is provided between the membrane support plate 20 and membrane 30, as shown most clearly in Figure 3. It is to be understood that while a conical membrane support plate surface is illustrated herein, many other configurations may be used in obtaining proper fluid distribution.

Referring to Figure 1, a second membrane support plate 40 is shown, comprising top half 40*a* and bottom half 40*b*, identically in the manner that membrane support plate 20 comprises top half 20*a* and bottom half 20*b*. Second membrane support plate 40 supports third membrane 48 and fourth membrane 50. Second membrane support plate 40 and membranes 48 and 50 supported thereby are identical to first membrane support plate 20 and membranes 28 and 30 supported thereby.

Likewise, a third membrane support plate 60 comprising top half 60*a* and bottom half 60*b* is provided for supporting membranes 68 and 70. Likewise, third membrane support plate 60 and membranes 68 and 70 supported thereby are identical to membrane support plates 20 and 40 and membranes 28, 30 and 48, 50, respectively, supported thereby.

It is to be understood that while, first, second and third membrane support plates 20, 40 and 60, respectively, are shown, the dialyzer or oxygenator may contain a much larger number of membrane support plates which support membranes and are constructed identically to membrane support plate 20. The membrane may be formed of conventional semipermeable membrane, such as Cuprophan® material, all as is well-known in the art. "CUPROPHAN" is a registered Trade Mark.

The membrane support plates define openings 76 which are aligned and into which are positioned grommets for closing the membranes supported by each membrane support plate. As illustrated in Figure 1, a grommet 78 is associated with membrane support plate 20 for closing first and second membranes 28, 30 respectively. Likewise, a grommet 80 is positioned in opening 76 adjacent second membrane support plate 40 for closing third and fourth membranes 48 and 50. A third grommet 82 is positioned in opening 76 adjacent third membrane support plate 60 for closing membranes 68 and 70. Additional grommets are positioned in the openings 76 of each other membrane support plate for closing the membranes supported by each membrane support plate.

Since each of the grommets is identical, the construction of grommet 78 will be explained in detail, referring to Figure 2. Grommet 78 comprises an upper ring 90 and a lower ring 92 which are ultrasonically welded to each other to close membranes 28 and 30. Each of the membranes is pre-punched so that when it overlies the membrane support plate (see Figure 4) openings in the membrane will align with blood openings 76 and 76′ and dialysate or oxygen openings 94, 95, 96 and 97.

Upper ring 90 defines a central opening 100 and is provided with a weld trap 102 annularly about the underside of ring 90. Lower ring 92 defines a central opening 104 and includes a shear joint 106 which operates during sonic welding in accordance with principles well known in the ultrasonic welding art. As a specific example, grommet 78 may be formed of Lexan® plastic. "LEXAN" is a registered Trade Mark.

Top ring portion 90 and bottom ring portion 92 are sonically welded together to fuse and form a closing means for closing the membranes supported by the membrane support plates. The central openings defined by the grommets form a blood manifolding path 110 which permits the blood to flow freely through this path and through the blood paths between adjacent membranes and indicated by the arrows illustrated in Figure 1.

It can be seen that each of the grommets 78, 80, 82, etc. close the membranes supported by an adjacent membrane support plate and each grommet is spaced from the other to define a blood flow path therebetween. Further, each grommet is independent of the other whereby the closing forces on each pair of membranes supported by a membrane support plate are independent of the closing forces on the other pair of membranes supported by other membrane support plates.

Although a grommet closure system is shown herein, it is to be understood that other closure systems may be used. For example, the membranes 28, 30 may be heat sealed or may be cement bonded instead of being closed by means of a grommet. It is preferred that each of the membrane pairs be closed in the same manner as the closure for the other membrane pairs.

In order to aid in understanding the fluid flow (e.g., the dialysate or oxygen flow) reference is made to Figures 4-11. Membrane support surface 22 includes a large number of cones 26 (illustrated in Figures 7 and 8) with larger size cones 126 interspersed throughout the surface area.

Each membrane support plate half 20*a* (or 20*b*, or 40*a* or 40*b*, etc.) has dialysate (or oxygen) openings 94, 95, 96 and 97. The dialysate (or oxygen) flow through openings 94-97 is as follows. The fluid flows through the openings and via channels 130, 132 and 134 (which are defined by underside 24) to openings 136 which extend through plate 20*a*. Openings 136 communicate with fluid manifold groove 140 which aid in the distribution of fluid through the volume defined by the cones 26, 126 and the membranes supported thereby. Angular distribution channels 141 and 142 communicate with channel 140 and transverse distribution channel 143 further aids in the proper distribution of fluid.

It can be seen that the fluid (e.g., dialysate or oxygen) path is effectively encapsulated with the blood compartment isolated from the fluid compartment in the blood manifold region, without compressive means being imposed on the blood manifolding region. Since the casing does not have to supply compressive forces to the blood manifolding region, the casing can be smaller and lighter, the means for closing the membrane pairs can be small and the dialyzer or oxygenator can be relatively thin. Further, the blood path is not a tortuous path through distribution channels of blood button, but is instead a smooth path, as most clearly shown in Figure 1.

WHAT WE CLAIM IS:–

1. Apparatus for the treatment of blood by means of a membrane, comprising a first membrane support plate and a second membrane support plate, each having means on opposite sides thereof for supporting a membrane and forming open volumes therebetween; first and second membranes supported on opposite sides of said first membrane support plate; third and fourth membranes supported on opposite sides of said second membrane support plate; said second membrane facing said third membrane to form a blood path between said second and third membranes; said volumes between each membrane support plate and each adjacent membrane comprising a fluid flow path, said membranes having apertures; a blood manifolding path which extends through said membrane support plates and through the apertures in the membranes; first closing means closing said first and second membranes together around the apertures therein; second closing means closing said third and fourth membranes together around the apertures therein; said first and second closing means each operating to segregate the blood path and said fluid flow path, said first and second closing means being spaced from each other to define a blood path therebetween and being independent of each other whereby the closing forces generated by said first closing means on said first and second membranes are independent of the closing forces generated by said second closing means on the third and fourth membranes.

2. Apparatus for effecting the treatment of blood by means of a stack of parallely disposed membranes, comprising means for isolating respective blood and treatment fluid compartments from each other in a blood manifold region, said isolating means comprising means for closing a first and second membrane about a first membrane support plate, means for closing a third and fourth membrane about a second membrane support plate, said second and third membranes facing each other to define a blood flow path therebetween, fluid distribution volumes defined between each membrane and its associated membrane support plate, said closing means being space from each other and defining a flow path between the second and third membranes, the closing means defining a blood manifolding path extending through said closing means membranes and membrane support plates without radial distribution channels in the closing means, said blood manifolding path permitting the blood to flow in the spacings between said closing means for flow between the membranes facing each other.

3. Apparatus for the treatment of blood by means of a membrane comprising a stack of parallel membranes and membrane support plates with each membrane support plate having a membrane positioned on opposite sides thereof; a blood manifolding path extending through said membranes; closing means sealing the membranes on opposite sides of each membrane support plate to each other around said blood manifolding path, said closing means being spaced from each other to define a blood path therebetween and being independent of each other, whereby the closing forces generated by one of the closing means on its respective membranes are independent of the closing forces generated by other closing means on their respective membranes.

4. Apparatus according to claim 1, 2 or 3, wherein each of said closing means comprises a sealed grommet, having an axial bore extending therethrough and forming a portion of said blood manifolding path.

5. Apparatus according to claim 1, 2 or 3, wherein said closing means comprise heat sealed membrane portions forming a portion of said blood manifolding path.

6. Apparatus according to claim 1, 2 or 3, wherein said closing means comprise adhesive bonded membrane portions forming a portion of said blood manifolding path.

7. Apparatus according to any preceding claim, wherein said membrane support plates are parallely positioned and said blood manifolding path comprises a path normal to the longitudinal axis of said membrane support plates.

8. Apparatus according to claim 1 or 2, wherein said fluid flow path comprises a dialysate path.

9. Apparatus according to claim 1 or 2, wherein said fluid path comprises an oxygen path.

10. Apparatus for the treatment of blood by means of a membrane, constructed substantially as herein described with reference to the accompanying drawings.

ERIC POTTER & CLARKSON
Chartered Patent Agents
14 Oxford Street,
Nottingham.

Printed for Her Majesty's Stationery Office by MULTIPLEX techniques ltd., St. Mary Cray, Kent. 1981. Published at the Patent Office, 25 Southampton Buildings, London WC2 1AY, from which copies may be obtained.

1591117 COMPLETE SPECIFICATION

3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 1

FIG. 1

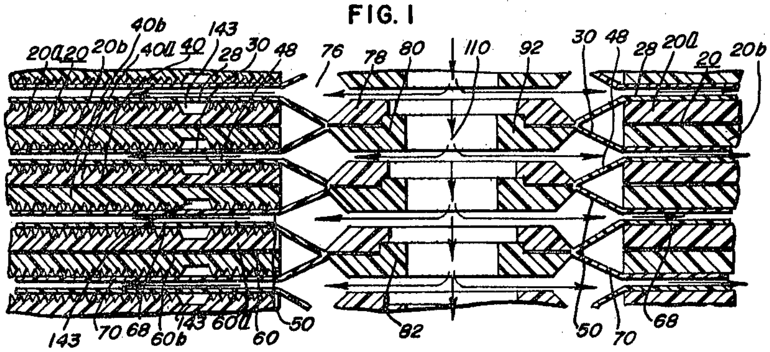


FIG. 2

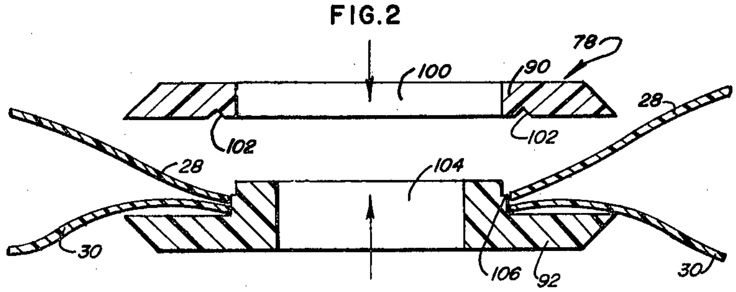
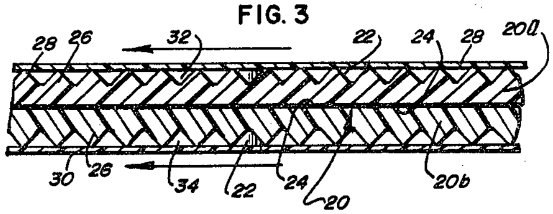


FIG. 3



1591117 COMPLETE SPECIFICATION

3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 2

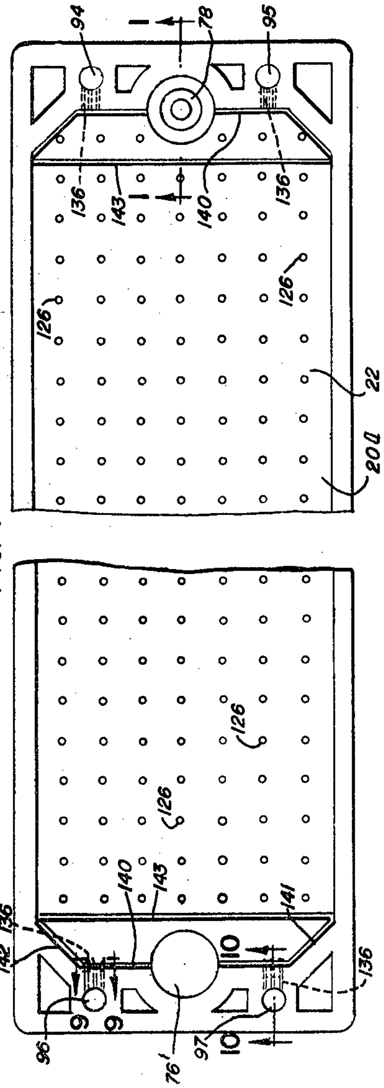


FIG. 4

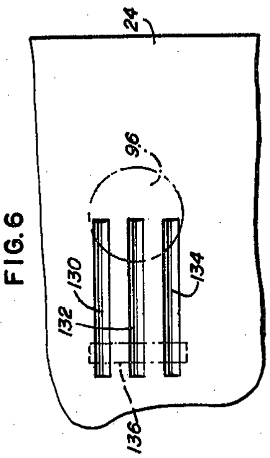


FIG. 6

FIG. 5

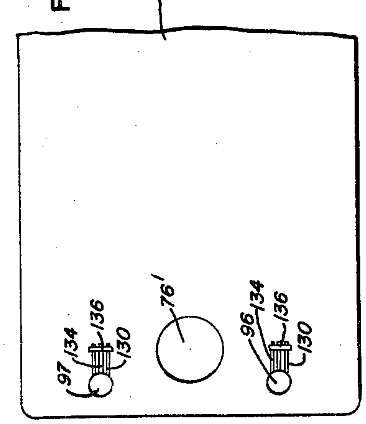


FIG. 7

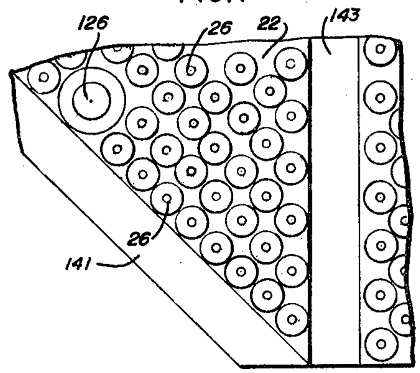


FIG. 8

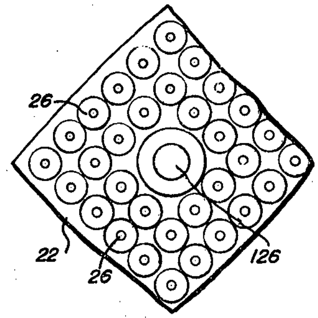


FIG. 9

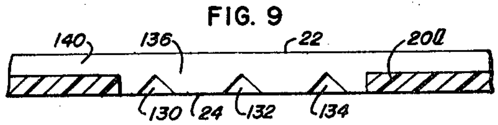


FIG. 10